K010620

MAY 1 7 2001

510(k) Summary

2/27/2001

Onux Medical, Inc., Contact Person:	John Rice
Trade or Proprietary Name:	None established
Common or Usual Name:	Endoscopic staple removal instrument
Classification Name:	Endoscope and/or Accessory

Devices to Which Equivalence is Claimed
The Salute staple removal instrument is substantially equivalent to the Ethicon Endopath™ ES Endoscopic Staple Extractor.

Description of Subject Device
The subject device is a manual instrument for endoscopic or open surgical procedures. It employs a trigger handle design with an actuation lever and 5mm shaft. A rod at the end of the shaft engages the underside of the staple and pulls it inside the shaft when the lever is actuated. When the lever is released, the staple is release from within the device. The instrument is re-useable and is sterilized by steam autoclave.

Intended Use of Subject Device
Both the Salute staple removal instrument and the Ethicon Endopath ES Endoscopic Staple Extractor are intended for laparoscopic or open removal of staples.

Comparison of Technical Aspects
Both the Salute staple removal instrument and the Endopath ES Staple Extractor are manual re-useable instruments for removing staples in either an open or laparoscopic surgical setting. They both engage the underside of the staple at the distal end of the device shaft. Both have levers that actuate the un-bending of the staple. While the lever is kept closed, the extracted staple is held by the device for removal to outside the surgical area. Releasing the lever expels the staple from the device shaft.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2001

Mr. John Rice
Vice President of Engineering
Onux Medical, Inc.
5 Merrill Drive
Hampton, New Hampshire 03842

Re: K010620
Trade/Device Name: Endoscopic Staple Removal Instrument
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ, KOG
Dated: February 27, 2001
Received: March 1, 2001

Dear Mr. Rice:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010620

Statement of Indications for Use

INDICATIONS

The Salute staple removal instrument is a re-useable instrument intended for laparoscopic or open removal of Salute staples.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010620